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EXAMINER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

1. This Office Action is in response to the amendment filed on September 18, 2008. Examiner acknowledges claims 20, 21, and 23-40 are pending in this application, with claims 1-19, and 22 having been cancelled, claims 20, 21, 23-25, and 27-37 having been currently amended, and claims 39 and 40 having been newly added.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, Applicant has amended the claim language to include the limitation of "a second part which secures the hygienic protection system"; however, it is unclear what the hygienic protection system is secured to. Because of this, Examiner is unsure as to how the removable hygienic protection system is secured within the oronasal face piece (24) and what is required to remove the hygienic protection system from the oronasal face piece. Appropriate correction is required.

Claim Rejections - 35 USC § 102

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 20 and 23-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Stern et al. (5,372,130).

As to Claim 20, Stern discloses a respirator face mask (10) providing physiological protection, comprising: an oronasal face piece (24) which is connectable to a respiratory gas source (18), said oronasal face piece (24) having a semi flexible lip element (26) with an edge (78) designed to position said oronasal face piece (24) on a user's face, and hygienic protection system (16) which are removably positioned (Column 6, Lines 15-17 and Column 10, Lines 7-16) at least partially inside said mask (10) and including a first part (16a) which provides hygienic protection and a second part (82) which secures said hygienic protection system, wherein the edge (78) of the semi flexible lip (26) returns toward the center of the oronasal face piece (24), defining an internal groove (represented by the gap between the edge 78 and the top portion of the semi-flexible lip 75) in the oronasal face piece (24), and said second part (82) of the hygienic protection system (16) expands radially in order to cooperate elastically with the internal groove (represented by the gap between the edge 78 and the top portion of the semi-flexible lip 75) of the oronasal face piece (24). Regarding the elastically cooperative interaction between the second part (82) of the hygienic protection system (16) and the internal groove (represented by the gap between the edge 78 and the top

portion of the semi-flexible lip 75) of the oronasal face piece (24), there is no recitation requiring the second part (82) of the hygienic protection system (16) to be made of an elastic material nor is there a recitation of any additional elements that would prevent the movement of the internal groove (represented by the gap between the edge 78 and the top portion of the semi-flexible lip 75) of the oronasal face piece (24), made from the semi-flexible lip, to cooperatively interact with the second part (82) of the hygienic protection system (16). Inherently, as these two elements are connected, the elastic nature of the internal groove and the movement of the elastic portion of the internal groove would result in a cooperative elastic interaction with the hygienic protection system. (Column 6, Line 40).

As to Claims 23 and 24, Stern discloses a thin lip insulation part (Figure 3: the bottom portion of element 82 located below the chin disconnected from the internal groove found at element 30 which protrudes and separates from element 30) of said hygienic protection system (16) prolongs, in at least one area of the second part (82) of said hygienic protection system (16) so as to extend a few millimeters beyond said edge of said semi flexible lip. As seen in Figure 3, the dimensions of the defined thin lip insulation part extend beyond the semi-flexible lip portion of the oronasal face mask (24) just below the user's chin.

As to Claims 25 and 26, Stern discloses the first part (16a) of said hygienic protection system (16) filters respiratory gas to protect the user from contamination. (Column 4, Lines 49-63).

As to Claim 27 and 28, Stern discloses the corrugated shape (Figures 3-6) of the hygienic protection system (16), where the corrugated shape is in the central area of the mask.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. (5,372,130).

As to Claim 29, the system of Stern/ Kaufman discloses a flexible structure placed between the hygienic protection means and the internal part of the semi-flexible lip element and extends beyond the semi-flexible lip element. Specifically, as seen in Figure 11 of Stern, the filter (16) extends beyond the perimeter of the mask to enable the user to grasp the outside portion of the filter and remove it. It is well known to use tabs, projections and cords to assist in the removing of one part relative to another. Stern exemplifies this by showing the ends of the filter extending beyond the mask that are capable of extracting the filter from the mask. The exact form by which the extraction is achieved is well within the realm of the artisan of ordinary skill. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention

was made to modify the removable filter of Stern to include cords for aiding in the removal of the filter from the mask.

8. Claims 21, 30-35, 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. (5,372,130) in view of Kaufman (3,757,777).

As to Claim 21, Stern discloses a respirator face mask (10) where the hygienic protection system (16) is made from two parts (16a and 82, respectively), yet Stern does not expressly disclose the first and second parts to be made of different materials. However, at the time the invention was made the use of different materials in the construction of removable filters was known. Specifically, Kaufman teaches the dual part filter system (a center portion made of filter media and the circumference made from a plastic) enables the mask to contour to the shape of the wearer while filtering the environment. (Column 2, Lines 45-51). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the two part hygienic protection system of Stern to include different materials for each part for the purpose of enhancing the sealing the device to the face of the patient and filtering contaminants.

As to Claim 30, the system of Stern/ Kaufman teaches the use of plastic to form the second part of the hygienic protection means and discloses any other material may be used. (Column 3, Lines 1-25). Intrinsically, as silicone is a plastic polymer, silicone is include as a device the second part can be made from. Furthermore, it should be noted that the portion of the recitation that claims the second part is made of silicone is

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directed to a process. Since the claim is an apparatus/product claim, patentable weight is only given to the end product. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is in the same as or obvious form a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

As to Claims 39 and 40, Stern discloses a respirator face mask (10) providing physiological protection, comprising: an oronasal face piece (24) which is connectable to a respiratory gas source (18), said oronasal face piece (24) having a semi flexible lip element (26) with an edge (78) designed to position said oronasal face piece (24) on a user's face, and hygienic protection system (16) which are removably positioned (Column 6, Lines 15-17 and Column 10, Lines 7-16) at least partially inside said mask (10) and including a first part (16a) which provides hygienic protection and a second part (lip securing part, 82) which secures said hygienic protection system, wherein the edge (78) of the semi flexible lip (26) returns toward the center of the oronasal face piece (24), defining an internal groove (represented by the gap between the edge 78 and the top portion of the semi-flexible lip 75) in the oronasal face piece (24), and said second part (lip securing part, 82) of the hygienic protection system (16) expands radially in order to cooperate elastically with the internal groove (represented by the gap between the edge 78 and the top portion of the semi-flexible lip 75) of the oronasal face

piece (24). Regarding the lip insulation part, Stern discloses a thin lip insulation part (Figure 3: the bottom portion of element 82 located below the chin disconnected from the internal groove found at element 30 which protrudes and separates from element 30) of said hygienic protection system (16) prolongs, in at least one area of the second part (82) of said hygienic protection system (16) so as to extend a few millimeters beyond said edge of said semi flexible lip. As seen in Figure 3, the dimensions of the defined thin lip insulation part extend beyond the semi-flexible lip portion of the oronasal face mask (24) just below the user's chin. Yet, Stern does not expressly disclose the second part (lip securing part) of the hygienic protection system is elastic. However, at the time the invention was made the use of different materials in the construction of removable filters was known. Specifically, Kaufman teaches the dual part filter system (a center portion made of filter media and the circumference made from a plastic) enables the mask to contour to the shape of the wearer while filtering the environment. (Column 2, Lines 45-51). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the two part hygienic protection system of Stern to include different materials for each part for the purpose of enhancing the sealing the device to the face of the patient and filtering contaminants.

As to Claim 31, Stern discloses the hygienic protection means is removable. (Column 2, Lines 15-17). As the device of Stern has an outer filter (14) the device is still operable for use whether the hygienic protection means is present or not and the semi-flexible lip element (26) would be in direct contact with the user's face.

As to Claims 32-34, and 38, the system of Stern/ Kaufman discloses a flexible structure placed between the hygienic protection means and the internal part of the semi-flexible lip element and extends beyond the semi-flexible lip element. Specifically Kaufman has straps (8) that extend beyond the semi-flexible lip element and around the head of the user to retain the hygienic protection means in place.

As to Claim 35, the system of Stern/ Kaufman discloses a three part filtering mask system. Specifically, Kaufman discloses a first part (1) designed to be pressed onto said user's face, by the effect of a pressure of respiratory gas inside said mask, when said mask is worn to provide a seal between said hygienic protection means and said user's face, a second part (2) located over an external area of said face semi-flexible lip element which, in absence of said hygienic protection means, would have been in contact with the user's face once said mask was in place on said user's face, and a third part (4) located outside the semi-flexible lip element and including a structural part providing a seal between the semi-flexible lip element and said hygienic protection means.

9. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. (5,372,130) in view of Kaufman (3,757,777) as applied to claim 35 above, and further in view of Martin (4,641,379).

As to Claim 36, the system of Stern and Kaufman teaches a respiratory mask with a structural part, yet does not expressly disclose the structural part exerting mechanical pressure on the semi-flexible lip element greater than the maximum

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pressure of respiratory gas which can prevail inside the mask. However, at the time the invention was made the specifics of the structural part was known. Specifically, Martin teaches a strap (10) for a mask (30) that extends around the circumference of the user's head providing a uniform pressure to the mask thereby allowing a greater degree of comfort to the user. (Figure 3, and Column 3, Lines 55-60). Therefore, it would have been obvious to one having ordinary skill in the art at time the invention was made to modify the system of Stern/Kaufman to include a structural part exerting a mechanical pressure on the user, for increasing the comfort of the wear of the mask by distributing the pressure uniformly.

10. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. (5,372,130) in view of Kaufman (3,757,777) as applied to claim 35 above, and further in view of Spector (4,597,781).

As to Claim 37, the system of Stern/Kaufman teaches a three part hygienic protection means with two of the three parts made of plastic, yet does not expressly disclose the third part of the filter is also made of plastic. However, at the time the invention was made the use of plastic in a filter was known. Specifically, Spector teaches the use of plastic filters in the filtration of air (Column 1, Lines 55-58).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Stern/Kaufman to include another portion made with a plastic for the purpose of providing filtering of coarse particles. Furthermore, it should be noted that the portion of the recitation that claims that the

three parts are formed of a single elastic film is directed to a process. Since the claim is an apparatus/product claim, patentable weight is only given to the end product. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is in the same as or obvious form a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Response to Arguments

11. Applicant's arguments with respect to claims 20, 21, and 23-40 have been considered but are moot in view of the new ground(s) of rejection.

Regarding Examiners use of prior art Stern under 35 U.S.C. 102(b) for claim 20 and dependants, Examiner carefully reconsidered of the prior art references utilizing the broadest reasonable interpretations of the claim language. This reconsideration of the prior art reference resulted determined that the Examiner had unintentionally read the limitations from the specification regarding the silicone portion of the hygienic protection means into the claim language to meet the understanding of the elastically cooperating interaction. However, broadly interpreted, the movement of an elastic piece connected to a non elastic piece will result in an elastic interaction between the two elements. Thus, in order to protect the integrity of Applicant's invention in the advent of allowance, correction to the rejection was required and necessitated by the newly amended claim

language as all of the recited elements including Applicant's newly added limitation of an internal groove were present in independent claim 20.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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